Amendments to the Claims:

The present listing of the claims replaces all past listings of the claims:

Listing of claims

Claims 1-49. (Canceled).

Claim 50. (Currently Amended) Method ~~of using~~ **for preparing an agent for gene transfer, which method comprises combining**

(i) a nucleic acid construct comprising at least one hormone responsive element (HRE) and a transgene, said at least one HRE being not functionally linked to the transgene, and

(ii) a hormone-hormone receptor complex ~~for preparing an agent for gene transfer~~.

Claim 51. (Previously Presented) The method of claim 50, wherein the transgene is selected from the group consisting of genes encoding a blood clotting factor, hormone genes, hormone receptor genes, growth factors, enzyme genes, genes encoding cytokines or lymphokines, genes encoding inhibitor substances, genes encoding substances that function as drugs or vaccines, and antisense sequences.

Claim 52. (Previously Presented) The method of claim 51, wherein the transgene is a gene encoding a blood clotting factor and the agent is suitable for treating hemophilia.

Claim 53. (Previously Presented) The method of claim 52, wherein the blood

clotting factor is a human blood clotting factor ~~and preferably is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (vWF)~~.

Claim 54. (Currently Amended) The method of claim 50, wherein the nucleic acid construct comprises 1 to 20~~, preferably 3 to 10~~ HRE(s).

Claim 55. (Currently Amended) The method of claim 50, wherein the at least one HRE is a steroid responsive element~~, preferably a progesterone responsive element (PRE)~~.

Claim 56. (Currently Amended) The method of claim 53, wherein the HRE is a **progesterone responsive element (PRE)** ~~PRE~~ and the blood clotting factor is factor IX~~, and preferably the factor IX has a nucleotide sequence of 689 to 2071 of SEQ ID NO:1~~.

Claim 57. (Previously Presented) The method of claim 54, wherein the HRE is a PRE and the blood clotting factor is factor VIII.

Claim 58. (Previously Presented) The method of claim 55, wherein the PRE has the double stranded DNA sequence comprised of the DNA sequences of SEQ ID NOs: 3 and 4.

Claim 59. (Previously Presented) The method of claim 50, wherein the construct further comprises functional DNA sequences selected from the group consisting of promoter sequences, enhancer sequences, silencer sequences, origin of

replication sequences, integrational sequences, marker genes and switch sequences.

Claim 60. (Currently Amended) The method of claim 59, wherein the construct further comprises a tissue-specific promoter~~, preferably an α-antitrypsin promoter~~.

Claim 61. (Previously Presented) The method according to claim 50, wherein the hormone-hormone receptor complex is a steroid-steroid receptor complex.

Claim 62. (Currently Amended) The method of claim 61, wherein ~~the~~ **a first** molar ratio of HRE within the nucleic acid construct to hormone receptor is from 1:1 to 1:10, ~~preferably 1:2 to 1:5~~, and/or ~~the~~ **a second** molar ratio of hormone to hormone receptor is at least 1000:1~~, preferably at least 10000:1~~.

Claim 63. (Previously Presented) The method of claim 61, wherein the receptor is a progesterone receptor and the steroid is progesterone or a progesterone derivative.

Claim 64. (Previously Presented) The method of claim 63, wherein the progesterone is natural micronized progesterone solubilized in a liphophilic matrix system and/or the progesterone receptor is hPR-A, hPR-B or comprises the nucleotide sequence of 557 to 933 SEQ ID NO:18.

Claim 65. (Currently Amended) A pharmaceutical composition comprising a nucleic acid construct comprising at least one **hormone responsive element (HRE)**

~~HRE~~ and a transgene ~~as defined in claim 50~~ and/or a vector comprising said nucleic acid construct, said at least one HRE being coupled to a hormone-hormone receptor complex.

Claim 66. (Previously Presented) The pharmaceutical composition of claim 65, wherein the hormone-hormone receptor complex is a steroid-steroid receptor complex.

Claim 67. (Previously Presented) The pharmaceutical composition of claim 65, wherein the transgene is a gene encoding a blood clotting factor.

Claim 68. (Previously Presented) The pharmaceutical composition of claim 67, wherein the blood clotting factor is factor IX.

Claim 69. (Previously Presented) The pharmaceutical composition of claim 67, wherein the blood clotting factor is factor VIII.

Claim 70. (Previously Presented) The pharmaceutical composition of claim 67, which is suitable for gene transfer~~, preferably for treating hemophilia~~.

Claim 71. (Currently Amended) A nucleic acid construct comprising at least one **hormone responsive element (HRE)** ~~HRE~~ and a transgene being a gene encoding a blood clotting factor, wherein one of said at least one HREs is not functionally linked to the transgene.

Claim 72. (Currently Amended) The nucleic acid construct of claim 71, wherein the blood clotting factor is a human blood clotting factor ~~and preferably is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (vWF)~~.

Claim 73. (Previously Presented) A vector comprising the nucleic acid construct of claim 71.

Claim 74. (Currently Amended) A transformed cell or transgenic organism comprising the nucleic acid construct ~~as defined in~~ of claim 71.

Claim 75. (Currently Amended) A composition of matter comprising
[[-]] (i) the nucleic acid construct ~~comprising at least one HRE and a transgene as defined in~~ of claim 71, and/or
[[-]] (ii) a vector comprising said nucleic acid construct, said at least one HRE being coupled to a hormone-hormone receptor complex.

Claim 76. (Currently Amended) A method for preparing the composition of matter ~~as defined in~~ of claim 75, which method comprises admixing the nucleic acid construct with the hormone receptor and the hormone.

Claim 77. (Currently Amended) A method for gene transfer which comprises administering ~~the~~ an agent ~~as defined in~~ of claim ~~50~~ 113 to an organism or to a cellular system.

Claim 78. (Currently Amended) A method for delivering into an organism or into a cellular system a nucleic acid encoding a transgene to be expressed in the cells of the organism or the cells of ~~the~~ a cellular system, which method comprises administering an agent ~~as defined in~~ of claim ~~59~~ 113 to the organism or to the cellular system so that ~~the~~ a hormone in ~~the~~ a composition interacts with ~~the~~ a cell membrane and therewith enhances diffusion and transport of the nucleic acid that is coupled to the hormone-hormone receptor complex across the membrane and into the cell.

Claim 79. (Previously Presented) The method of claim 78, wherein a nucleic acid encoding human factor VIII or factor IX is delivered into the cell.

Claim 80. (Previously Presented) A method of treating blood clotting disorders comprising administering a therapeutically effective amount of the pharmaceutical composition of claim 67 to an organism or to a cellular system.

Claim 81. (Previously Presented) A method of treating hemophilia B, comprising administering a therapeutically effective amount of the pharmaceutical composition of claim 68 to an organism or to a cellular system.

Claim 82. (Previously Presented) A method of treating hemophilia A, comprising administering a therapeutically effective amount of the pharmaceutical composition of claim 69 to an organism or to a cellular system.

Claim 83. (Currently Amended) Method ~~of using~~ for preparing an agent for treating hemophilia, which method comprising combining

(i) a nucleic acid construct comprising at least one hormone responsive element (HRE) and a transgene wherein the transgene is a gene encoding a blood clotting factor and the at least one HRE is functionally linked to the transgene, and

(ii) a hormone-hormone receptor complex ~~for preparing an agent for treating hemophilia~~.

Claim 84. (Currently Amended) The method of claim 83, wherein the blood clotting factor is a human blood clotting factor ~~and preferably is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (vWF)~~.

Claim 85. (Currently Amended) The method of claim 83, wherein the nucleic acid construct comprises 1 to 20~~, preferably 3 to 10~~ HRE(s).

Claim 86. (Currently Amended) The method of claim 83, wherein the at least one HRE is a steroid responsive element~~, preferably a progesterone responsive element (PRE)~~.

Claim 87. (Currently Amended) The method of claim 84, wherein the HRE is a PRE and the blood clotting factor is factor IX~~, preferably the factor IX has a nucleotide sequence of 689 to 2071 of SEQ ID NO:1~~.

Claim 88. (Previously Presented) The method of claim 84, wherein the HRE is a PRE and the blood clotting factor is factor VIII.

Claim 89. (Previously Presented) The method of claim 86, wherein the PRE has the double stranded DNA sequence comprised of the DNA sequences of SEQ ID NOs: 3 and 4.

Claim 90. (Previously Presented) The method of claim 83, wherein the construct further comprises functional DNA sequences selected from the group consisting of promoter sequences, enhancer sequences, silencer sequences, origin of replication sequences, integrational sequences, marker genes and switch sequences.

Claim 91. (Currently Amended) The method of claim 90, wherein the construct further comprises a tissue-specific promoter~~, preferably an α-antitrypsin promoter~~.

Claim 92. (Previously Presented) The method according to claim 83, wherein the hormone-hormone receptor complex is a steroid-steroid receptor complex.

Claim 93. (Currently Amended) The method of claim 92, wherein ~~the~~ **a first** molar ratio of HRE within the nucleic acid construct to hormone receptor is from 1:1 to 1:10, ~~preferably 1:2 to 1:5~~, and/or ~~the~~ **a second** molar ratio of hormone to hormone receptor is at least 1000:1~~, preferably at least 10000:1~~.

Claim 94. (Previously Presented) The method of claim 92, wherein the receptor is a progesterone receptor and the steroid is progesterone or a progesterone derivative.

Claim 95. (Previously Presented) The method of claim 94, wherein the progesterone is natural micronized progesterone solubilized in a liphophilic matrix system and/or the progesterone receptor is hPR-A, hPR-B or comprises the nucleotide sequence of 557 to 933 SEQ ID NO:18.

Claim 96. (Previously Presented) A method for gene transfer which comprises administering the agent as defined in claim 83 to an organism or to a cellular system.

Claim 97. (Currently Amended) A method for delivering into an organism or into a cellular system a nucleic acid encoding a transgene to be expressed in the cells of the organism or the cells of the cellular system, which method comprises administering an agent ~~as defined in of~~ claim ~~83~~ 114 to the organism or to the cellular system so that ~~the~~ a hormone in ~~the~~ a composition interacts with ~~the~~ a cell membrane and therewith enhances diffusion and transport of the nucleic acid that is coupled to the hormone-hormone receptor complex across the membrane and into the cell.

Claim 98. (Previously Presented) The method of claim 97, wherein a nucleic acid encoding human factor VIII or factor IX is delivered into the cell.

Claim 99. (New) The method of claim 53, wherein the human blood clotting factor is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (vWF).

Claim 100. (New) The method of claim 54, wherein the nucleic acid construct comprises 3 to 10 HRE(s).

Claim 101. (New) The method of claim 55, wherein the at least one HRE is a progesterone responsive element (PRE).

Claim 102. (New) The method of claim 56, wherein the factor IX has a nucleotide sequence of 689 to 2071 of SEQ ID No:1.

Claim 103. (New) The method of claim 60, wherein the tissue-specific promoter is an α-antitrypsin promoter.

Claim 104 (New) The method of claim 62, wherein the first molar ratio of HRE within the nucleic acid construct to hormone receptor is from 1:2 to 1:5, and/or the second molar ratio of hormone to hormone receptor is at least 10000:1.

Claim 105 (New) The pharmaceutical composition of claim 70, which is suitable for treating hemophilia.

Claim 106. (New) The nucleic acid construct of claim 72, wherein the human blood clotting factor is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (vWF).

Claim 107. (New) The nucleic acid construct of claim 106, wherein the human blood clotting factor is factor VIII.

Claim 108 (New) The method of claim 84, wherein the human blood clotting factor is selected from the group consisting of factor VIII, factor IX, and von Willebrand Factor (WF).

Claim 109 (New) The method of claim 85, wherein the nucleic acid construct comprises 3 to 10 HRE(s).

Claim 110 (New) The method of claim 86, wherein the at least one HRE is a progesterone responsive element (PRE).

Claim 111 (New) The method of claim 87, wherein the factor IX has a nucleotide sequence of 689 to 2071 of SEQ ID No:1.

Claim 112 (New) The method of claim 91, wherein the tissue-specific promoter is an α-antitrypsin promoter.

Claim 113 (New) The method of claim 93, wherein the first molar ratio of HRE within the nucleic acid construct to hormone receptor is from 1:2 to 1:5, and/or the second molar ratio of hormone to hormone receptor is at least 10000:1.

Claim 114. (New) An agent for gene transfer comprising:

(i) a nucleic acid construct comprising at least one hormone responsive element (HRE) and a transgene, said at least one HRE being not functionally linked to the transgene, and

(ii) a hormone-hormone receptor complex.

Claim 115. (New) An agent for treating hemophilia comprising:

(i) a nucleic acid construct comprising at least one hormone responsive element (HRE) and a transgene wherein the transgene is a gene encoding a blood clotting factor and the at least one HRE is functionally linked to the transgene, and

(ii) a hormone-hormone receptor complex.

Applicants: Charlotte Hauser-Funke
Application No. 09/913,631
Combined Amendment and Response to Restriction Requirement

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.